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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,121	01/18/2002	Randolph M. Howes	2514-0051-01	7866

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/050,121	HOWES, RANDOLPH M.	
	Examiner	Art Unit	
	Frank I Choi	1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Frank Choi

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

Continuation of 5. does NOT place the application in condition for allowance because: Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 208 USPQ 871 (CCPA 1981). Contrary to Applicant's arguments Schraufstatter et al. does not simply describe currrent hypotheses on the functioning of eukaryotic cells. The action of hypochlorite on target cells was actually tested with result of effects on the plasma membranes being dose dependent in that increasing doses of hypochlorite led to cell lysis. The action of hydrogen peroxide on the target cells was also tested which also resulted in cell death by different mechanisms from hypochlorite. Clearly, the ability of administered hypochlorite and hydroge peroxide to kill target cells is applicable to treatment of tumor cells and, therefore, treatment of cancer. The purpose of McCaughan et al. was to elucidate that the singlet oxygen produced by the combination of hypochlorite and peroxide was no different than the singlet oxygen produced by the photooxidation or photodynamic process, which singlet oxygen is acknowledged by Applicant to known to be effective in treating tumor cells and cancer. Applicant notes that Dr. Foote, as the discoverer of the reaction of peroxide and hypochlorite to produce singlet oxygen, could have proceeded to the present invention but did not, supposedly as some anecdotal evidence relative to non-obviousness. However, what Dr. Foote did or did not do with the knowledge is not the standard for determining obviousness. Contrary to Applicant's arguments Beattie et al. is relevant to rejection as Applicant claims the use of separate sources of hypochlorite and peroxide at the point of use. Applicant acknowledges that it is known that singlet oxygen is a extremely short lived species. As such, one of ordinary skill in the art would want to avoid mixing the peroxide and hypochlorite as long as possible. Beattie et al. provides the means by which the mixing can be avoided until the very point of use. Applicant argues that there is nothing in the art that suggests that hypochlorite or peroxide can be safely adminitered for tumorcidal effect in vivo. However, safety is more properly the providence of the FDA . Applicant argues that thereis nothing that suggests that these two reactants can be combined at target site to achieve tumoricidal effect, however, as indicated above the combination of hypochlorite and peroxide are known to produce singlet oxygen and singlet oxygen is known to be effective against tumor cells and cancer. The purpose of Ex parte Rubin, In re Burhans and In re Gibson is solely for the purpose of asserting that simultaneous or sequential administration of the proxide and hypochlorite does not patentably distinguish from the teachings of the prior art that the mixture of hypochlorite and peroxide will be effective in treating tumor cells and cancer. Applicant argues that because the American Cancer Society has stated that there is no evidence that hydrogen peroxide has value as a treatment for cancer or other diseases and that the MSDS for bleach is shows that bleach is toxic that this is evidence of unobviousness sufficient to overcome the rejection herein. However, it is hardly unexpected that hydrogen peroxide and hypochlorite are toxic. In fact, all medicines are to one extent or another toxic to the human body. Applicant acknowledges in the Specification that singlet oxygen is itself toxic, however, this has not stopped its use in the treatment of tumor cells and cancer. With respect to the American Society Article, despite its conclusions, it does indicate that there is some evidence of effective use of hydrogen peroxide in the treatment of tumor cells and cancer. With respect to the MSDS, the MSDS is of limited relevance as the concentration of sodium hypochlorite in the MSDS is 5.25%. Examine notes that Applicant's arguments, assuming that they were valid, appear to be relevant to the enablement or lack thereof of Applicant's own invention, as the Specification, using Applicant's own standard, does not appear to show any evidence that the claimed invention would be effective in treating tumor cells or cancer (the example set forth in the Specification appears to be prophetic in nature as opposed to actual results).